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Date:	Client & Matter Number:	No. Pages (including this one):
September 30, 2009	**018891-004310US**	**34**
To:	At Fax Number:	Confirmation Phone Number:
Examiner Christina Bradley	**571 273 9044**	**571 272 9044**

From: Mark H. Hopkins, Ph.D. **(907)**

Message:

Please see the attached Informal Amendment (after allowance) not to be entered, solely for the purpose of the Examiner's review and remarks.

Original Will:		BE SENT BY MAIL		BE SENT BY COURIER		BE SENT BY MESSENGER	X	NOT BE SENT

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PATENT
Attorney Docket No.: 018891-004310US
INFORMAL AMENDMENT NOT FOR ENTRY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Senter et al.

Application No.: 10/522,911

Filed: July 7, 2005

For: DRUG CONJUGATES AND THEIR USE FOR TREATING CANCER, AN AUTOIMMUNE DISEASE OR AN INFECTIOUS DISEASE

Customer No.: 51535

Confirmation No. 7034

Examiner: Christina Bradley

Technology Center/Art Unit: 1654

INFORMAL AMENDMENT AFTER ALLOWANCE UNDER 37 CFR § 1.312 NOT FOR ENTRY

DRAFT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

In response to the Notice of Allowance mailed September 25, 2009, please amend the above-identified application as follows:

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims which begins on page 3 of this paper.

Remarks/Arguments begin on page 33 of this paper.

PAGE 2/35 * RCVD AT 9/30/2009 7:15:33 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-6/27 * DNIS:2739044 * CSID:9254728895 * DURATION (mm-ss):05-12

Amendments to the Specification:

Please amend paragraph at page 1 between title of the application and the Field of Invention: with the following amended paragraph:

This application ~~claims the benefit~~ is an application filed under 35 U.S.C. § 371 as a national stage application of International Application No. PCT/US2003/24209, filed July 31, 2003; which further claims the benefit under 35 U.S.C. § 119(e) of United States provisional application No. 60/400,403, filed July 31, 2002, which is incorporated by reference herein in its entirety.

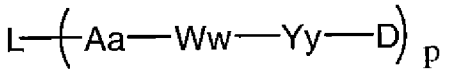
PAGE 3/35 * RCVD AT 9/30/2009 7:15:33 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-6/27 * DNIS:2739044 * CSID:9254728895 * DURATION (mm-ss):05-12

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1. (Currently amended) A compound of the Formula Ia:



Ia ;

or a pharmaceutically acceptable salt [or]thereof,

wherein,

L- is a Ligand unit;

-A- is a Stretcher unit;

a is 1;

each -W- is independently an Amino Acid unit;

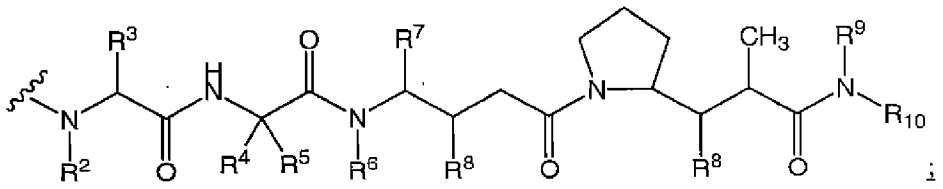
-Y- is a self-immolative Spacer unit;

w is an integer ranging from 2 to 12;

y is 1 or 2;

p ranges from 1 to about 20; and

-D is a Drug unit of the formula:



~~wherein,~~ the wavy line indicates the point of attachment to the Spacer unit, and independently at each location:

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R^2 is selected from the group consisting of -H and -C_1-C_8 alkyl;

R^3 is selected from the group consisting of -H, -C_1-C_8 alkyl, -C_3-C_8 carbocycle, -O-(C_1-C_8 alkyl), -aryl, -C_1-C_8 alkyl-aryl, -C_1-C_8 alkyl-(C_3-C_8 carbocycle), -C_3-C_8 heterocycle and -C_1-C_8 alkyl-(C_3-C_8 heterocycle);

R^4 is selected from the group consisting of -H, -C_1-C_8 alkyl, -C_3-C_8 carbocycle, -O-(C_1-C_8 alkyl), -aryl, -C_1-C_8 alkyl-aryl, -C_1-C_8 alkyl-(C_3-C_8 carbocycle), -C_3-C_8 heterocycle and -C_1-C_8 alkyl-(C_3-C_8 heterocycle) ~~wherein;~~ R^5 is selected from the group consisting of -H and -methyl; or R^4 and R^5 join and form a ring with the carbon atom to which they are attached and R^4 and R^5 have the formula -(CR^aR^b)$_n$- ~~wherein;~~ R^a and R^b are independently selected from the group consisting of -H, -C_1-C_8 alkyl and -C_3-C_8 carbocycle and n is selected from the group consisting of 2, 3, 4, 5 and 6;

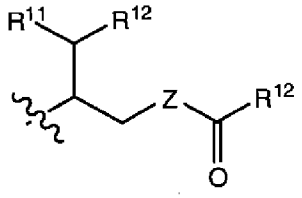
R^6 is selected from the group consisting of -H and -C_1-C_8 alkyl;

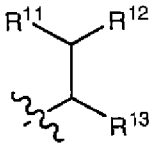
R^7 is selected from the group consisting of -H, -C_1-C_8 alkyl, -C_3-C_8 carbocycle, -O-(C_1-C_8 alkyl), -aryl, -C_1-C_8 alkyl-aryl, -C_1-C_8 alkyl-(C_3-C_8 carbocycle), -C_3-C_8 heterocycle and -C_1-C_8 alkyl-(C_3-C_8 heterocycle);

each R^8 is independently selected from the group consisting of -H, -OH, -C_1-C_8 alkyl, -C_3-C_8 carbocycle and -O-(C_1-C_8 alkyl);

R^9 is selected from the group consisting of -H and -C_1-C_8 alkyl;

R^{10} is selected from the group consisting of:



and


;

Z is -O-, -S-,-NH- or -N(R^{14})-;

R^{11} is selected from the group consisting of -H, -OH, -NH_2, -NHR^{14}, -N(R^{14})$_2$, -C_1-C_8 alkyl, -C_3-C_8 carbocycle, -O-(C_1-C_8 alkyl), -aryl, -C_1-C_8 alkyl-aryl, -C_1-C_8 alkyl-(C_3-C_8

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carbocycle), -C_3-C_8 heterocycle and -C_1-C_8 alkyl-(C_3-C_8 heterocycle); or R^{11} is an oxygen atom which forms a carbonyl unit (C=O) with the carbon atom to which it is attached and a hydrogen atom on this carbon atom is replaced by one of the bonds in the (C=O) double bond;

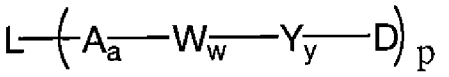
each R^{12} is independently selected from the group consisting of -aryl and -C_3-C_8 heterocycle;

R^{13} is selected from the group consisting of -H, -OH, -NH_2, -NHR^{14}, -$N(R^{14})_2$, -C_1-C_8 alkyl, -C_3-C_8 carbocycle, -O-(C_1-C_8 alkyl), -aryl, -C_1-C_8 alkyl-aryl, -C_1-C_8 alkyl-(C_3-C_8 carbocycle), C_3-C_8 heterocycle and -C_{1-8} alkyl-(C_3-C_8 heterocycle); and

each R^{14} is independently -H or -C_1-C_8 alkyl.

2-6. (Canceled)

7. (Currently amended) A compound of the formula Ia:



Ia

or a pharmaceutically acceptable salt thereof,

wherein,

L- is a Ligand unit;

-A- is a Stretcher unit;

a is 1;

each -W- is independently an Amino Acid unit;

-Y- is a self-immolative Spacer unit;

w is an integer ranging from 2 to 12;

y is 1 or 2;

p ranges from 1 to about 20; and

-D is a Drug unit having the structure:

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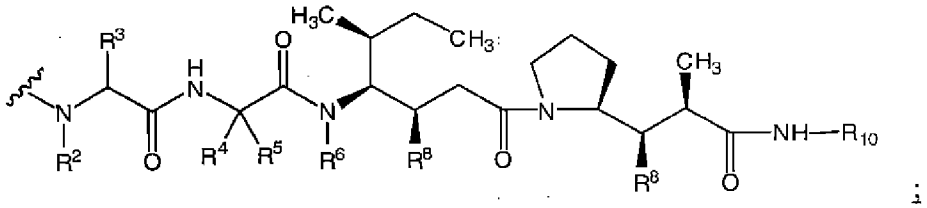


~~or a pharmaceutically acceptable salt thereof,~~

~~wherein,~~ the wavy line [is] indicates the point of attachment to the Spacer unit, and independently at each location:

R^2 is selected from the group consisting of -H and -methyl;

R^3 is selected from the group consisting of -H, -methyl, and -isopropyl;

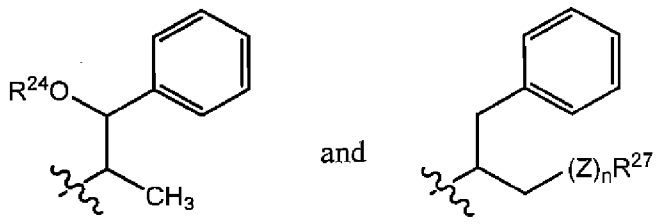
R^4 is selected from the group consisting of -H and -methyl;

R^5 is selected from the group consisting of -isopropyl, -isobutyl, -sec-butyl, -methyl and -t-butyl or R^4 and R^5 join[,] and form a ring with the carbon atom to which they are attached and R^4 and R^5 have the formula $-(CR^aR^b)_n-$ ~~where;~~ R^a and R^b are independently selected from the group consisting of -H, $-C_1$-C_8 alkyl, and $-C_3$-C_8 carbocycle, and n is selected from the group consisting of 2, 3, 4, 5 and 6;

R^6 is selected from the group consisting of -H and -methyl;

each R^8 is independently selected from the group consisting of -OH, -methoxy and -ethoxy;

R^{10} is selected from the group consisting of:



R^{24} is selected from the group consisting of H and $-C(O)R^{25}-$; ~~wherein~~ R^{25} is selected from the group consisting of $-C_1$-C_8 alkyl, $-C_3$-C_8 carbocycle, -aryl, $-C_1$-C_8 alkyl-aryl, $-C_1$-C_8 alkyl-(C_3-C_8 carbocycle), $-C_3$-C_8 heterocycle and $-C_1$-C_8 alkyl-(C_3-C_8 heterocycle);

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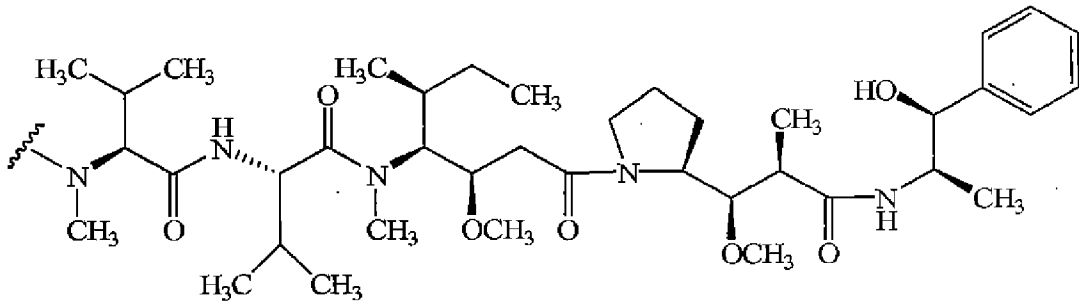
Z is -O-, -NH-, -OC(O)-, -NHC(O)-, or -NR^{28}C(O)-; ~~where~~ R^{28} is selected from the group consisting of -H and -C_1-C_8 alkyl;

n is 0 or 1; and

R^{27} is selected from the group consisting of -H, -N_3, -C_1-C_8 alkyl, -C_3-C_8 carbocycle, -aryl, -C_1-C_8 alkyl-aryl, -C_1-C_8 alkyl-(C_3-C_8 carbocycle), -C_3-C_8 heterocycle and -C_1-C_8 alkyl-(C_3-C_8 heterocycle) when n is 0; and R^{27} is selected from the group consisting of -H, -C_1-C_8 alkyl, -C_3-C_8 carbocycle, -aryl, -C_1-C_8 alkyl-aryl, -C_1-C_8 alkyl-(C_3-C_8 carbocycle), -C_3-C_8 heterocycle and -C_1-C_8 alkyl-(C_3-C_8 heterocycle) when n is 1.

8. (Canceled)

9. (Currently amended) [A]The compound or a pharmaceutically acceptable salt of the compound of claim 1 wherein -D is a Drug unit having the structure:



10-16. (Canceled)

17. (Currently amended) [A]The compound or a pharmaceutically acceptable salt of the compound of claim 1 or claim 7 wherein the Ligand unit is an antibody.

18. (Currently amended) The compound or a pharmaceutically acceptable salt of the compound of claim 17 wherein the antibody is a monoclonal antibody.

19. (Currently amended) The compound or a pharmaceutically acceptable salt of the compound of claim 18 wherein the monoclonal antibody specifically binds the CD30 antigen, the CD20 antigen, the Lewis X or Y antigen, the CD33 antigen, the CD38 antigen, the CEA antigen, the CD19 antigen, the CA15-3 antigen or the epidermal growth factor antigen.

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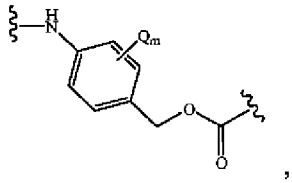
20. (Currently amended) The compound or a pharmaceutically acceptable salt of the compound of claim 1 wherein -Yy- is:

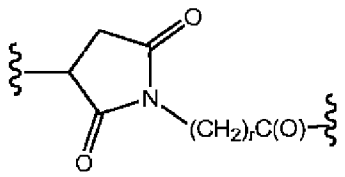


,

Q is selected from the group consisting of -C_1-C_8 alkyl, -O-(C_1-C_8 alkyl), -halogen, -nitro and -cyano; and

m is an integer ranging from 0-4, the amino terminus of -Yy- forming a bond with the Amino acid unit and the other terminus of -Yy- forming a bond with the Drug unit.

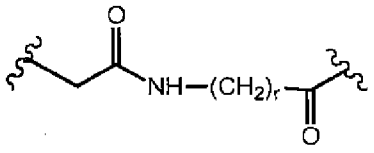
21. (Currently amended) The compound or a pharmaceutically acceptable salt of the compound of claim 1 wherein -A- is:



,

and r is an integer ranging from 1-10, the carbonyl terminus of -A- forming a bond with the Amino Acid unit and the succinimido terminus of -A- forming a bond with the Ligand unit.

22. (Currently amended) The compound or a pharmaceutically acceptable salt of the compound of claim 1 wherein -A- is:



,

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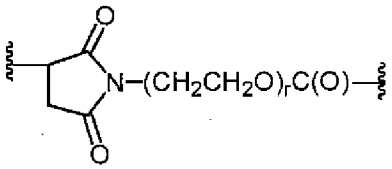
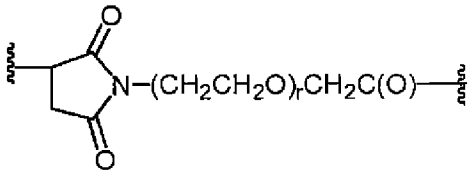
and r is an integer ranging from 1-10, the carbonyl terminus of -A- forming a bond with the Amino Acid unit and the amidomethyl terminus of -A- forming a bond with the Ligand unit.

23. (Currently amended) The compound or a pharmaceutically acceptable salt of the compound of claim 1 wherein -A- is:



and r is an integer ranging from 1-10, the carbonyl terminus of -A- forming a bond with the Amino acid unit and the succinimido terminus of -A- forming a bond with the Ligand unit.

24. (Currently amended) The compound or a pharmaceutically acceptable salt of the compound of claim 1 wherein -A- is:



and r is an integer ranging from 1-10, the carbonyl terminus of -A- forming a bond with the Amino acid unit and the succinimido terminus of -A- forming a bond with the Ligand unit.

25. (Currently amended) The compound or a pharmaceutically acceptable salt of the compound of claim 1 wherein -A- is:

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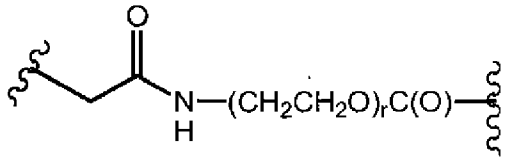
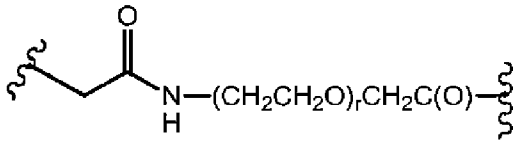


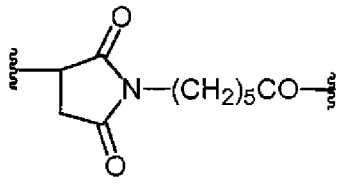
and r is an integer ranging from 1-10, the carbonyl terminus of -A- forming a bond with the Amino acid unit and the amidomethyl terminus of -A- forming a bond with the Ligand unit.

26. (Currently amended) The compound or a pharmaceutically acceptable salt of the compound of claim 1 wherein -A- is:



the carbonyl terminus of -A- forming a bond with the Amino acid unit and the amidomethyl terminus of -A- forming a bond with the Ligand unit.

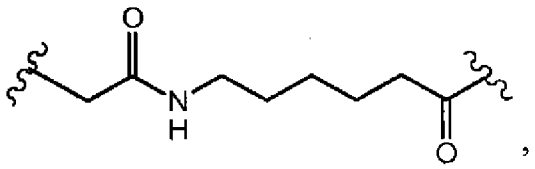
27. (Currently amended) The compound or a pharmaceutically acceptable salt of the compound of claim 21 wherein -A- is:



the carbonyl terminus of -A- forming a bond with the Amino acid unit and the succinimido terminus of -A- forming a bond with the Ligand unit.

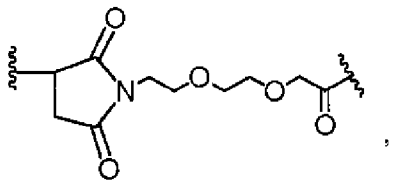
28. (Currently amended) The compound or a pharmaceutically acceptable salt of the compound of claim 22 wherein -A- is:

PAGE 11/35 * RCVD AT 9/30/2009 7:15:33 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-6/27 * DNIS:2739044 * CSID:9254728895 * DURATION (mm-ss):05-12



the carbonyl terminus of -A- forming a bond with the Amino acid unit and the amidomethyl terminus of -A- forming a bond with the Ligand unit.

29. (Currently amended) The compound or a pharmaceutically acceptable salt of the compound of claim 24 wherein -A- is:

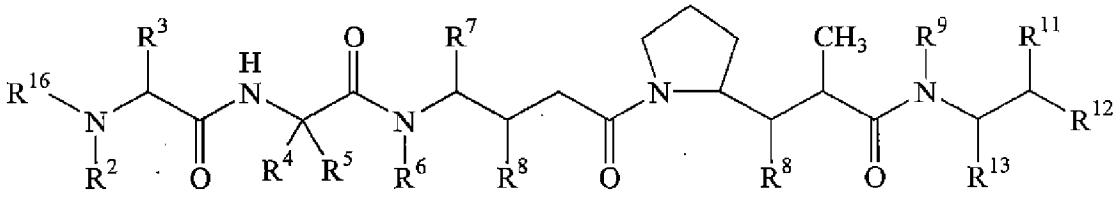


the carbonyl terminus of -A- forming a bond with the Amino acid unit and the succinimido terminus of -A- forming a bond with the Ligand unit.

30. (Currently amended) The compound or a pharmaceutically acceptable salt of the compound of claim 1 wherein -W_w- is -Phenylalanine-Lysine-, the amino terminus of -W_w- forming a bond with the Stretcher unit and the C- terminus of -W_w-forming a bond with the Spacer unit.

31-43. (Canceled)

44. (Currently amended) A compound of the formula:



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or a pharmaceutically acceptable salt thereof;

wherein, independently at each location:

R^2 is selected from the group consisting of -H and -C_1-C_8 alkyl;

R^3 is selected from the group consisting of -H, -C_1-C_8 alkyl, -C_3-C_8 carbocycle, -O-(C_1-C_8 alkoxy), -aryl, -C_1-C_8 alkyl-aryl, -C_1-C_8 alkyl-(C_3-C_8 carbocycle), -C_3-C_8 heterocycle and -C_1-C_8 alkyl-(C_3-C_8 heterocycle);

R^4 is selected from the group consisting of -H, -C_1-C_8 alkyl, -C_3-C_8 carbocycle, -O-(C_1-C_8 alkoxy), -aryl, -C_1-C_8 alkyl-aryl, -C_1-C_8 alkyl-(C_3-C_8 carbocycle), -C_3-C_8 heterocycle and -C_1-C_8 alkyl-(C_3-C_8 heterocycle) ~~wherein;~~ R^5 is selected from the group consisting of -H and -methyl; or R^4 and R^5 join and form a ring with the carbon atom to which they are attached and R^4 and R^5 have the formula: -(CR^aR^b)$_n$- ~~wherein;~~ R^a and R^b are independently selected from the group consisting of -H, -C_1-C_8 alkyl and -C_3-C_8 carbocycle and n is selected from the group consisting of 2, 3, 4, 5 and 6;

R^6 is selected from the group consisting of -H and -C_1-C_8 alkyl;

R^7 is selected from the group consisting of -H, -C_1-C_8 alkyl, -C_3-C_8 carbocycle, -O-(C_1-C_8 alkoxy), -aryl, -C_1-C_8 alkyl-aryl, -C_1-C_8 alkyl-(C_3-C_8 carbocycle), -C_3-C_8 heterocycle and -C_1-C_8 alkyl-(C_3-C_8 heterocycle);

each R^8 is independently selected from the group consisting of -H, -OH, -C_1-C_8 alkyl, -C_3-C_8 carbocycle and -O-(C_1-C_8 alkoxy);

R^9 is selected from the group consisting of -H and -C_1-C_8 alkyl;

R^{11} is selected from the group consisting of -H, -OH, -NH_2, -NHR^{14}, -$N(R^{14})_2$, -C_1-C_8 alkyl, -C_3-C_8 carbocycle, -O-(C_1-C_8 alkyl), -aryl, -C_1-C_8 alkyl-aryl, -C_1-C_8 alkyl-(C_3-C_8 carbocycle), -C_3-C_8 heterocycle and -C_1-C_8 alkyl-(C_3-C_8 heterocycle); or R^{11} is an oxygen atom which forms a carbonyl unit (C=O) with the carbon atom to which it is attached and a hydrogen atom on this carbon atom is replaced by one of the bonds in the (C=O) double bond;

each R^{12} is independently selected from the group consisting of -aryl and -C_3-C_8 heterocycle;

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R^{13} is selected from the group consisting of -H, -OH, $-NH_2$, $-NHR^{14}$, $-N(R^{14})_2$, $-C_1$-C_8 alkyl, $-C_3$-C_8 carbocycle, $-O-(C_1$-C_8 alkoxy), -aryl, $-C_1$-C_8 alkyl-aryl, $-C_1$-C_8 alkyl-(C_3-C_8 carbocycle), $-C_3$-C_8 heterocycle and $-C_1$-C_8 alkyl-(C_3-C_8 heterocycle);

each R^{14} is independently -H or $-C_1$-C_8 alkyl;

R^{16} is A'a-Ww-Yy-

~~wherein~~

each -W- is independently an Amino Acid unit;

-Y- is a self-immolative Spacer unit;

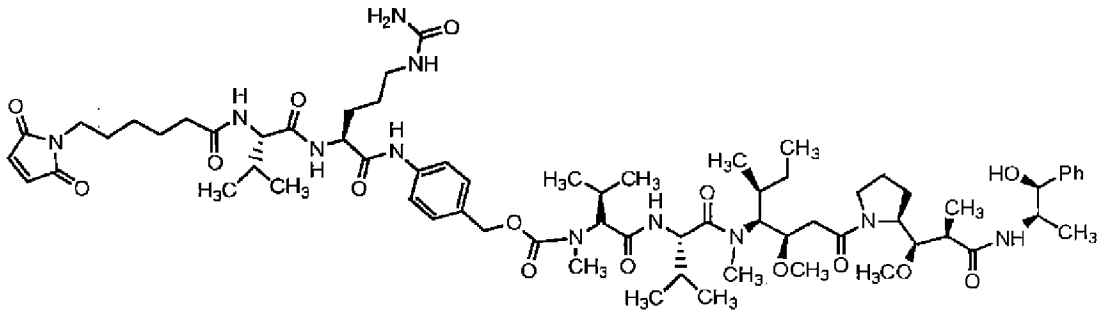
w is an integer ranging from 2 to 12;

y is 1 or 2;

-A' is a Stretcher unit; and

a is 1.

45. (Currently amended) The compound of claim 44 having the structure:



or a pharmaceutically acceptable salt thereof.

46. (Currently amended) The compound of claim 44 having the structure:

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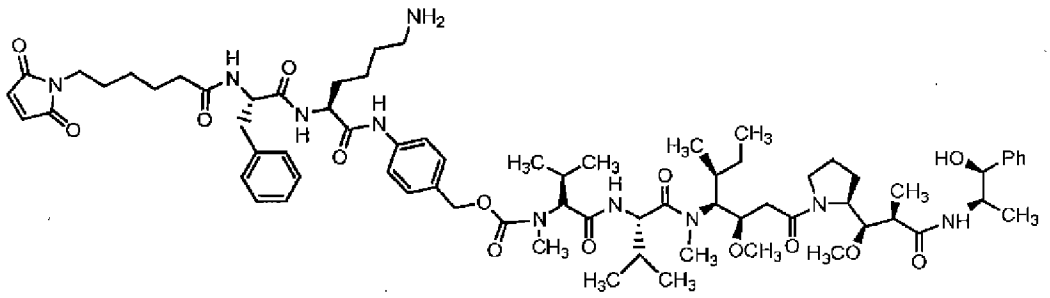
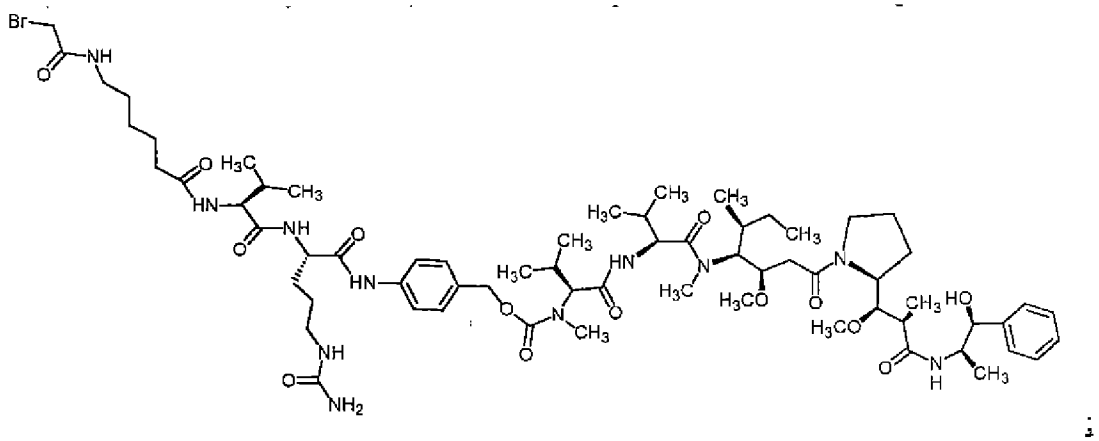


or a pharmaceutically acceptable salt thereof.

47. (Canceled)

48. (Currently amended) The compound of claim 44 having the structure:



or a pharmaceutically acceptable salt thereof.

49-51. (Canceled)

52. (Currently amended) The compound of claim 44 having the structure:

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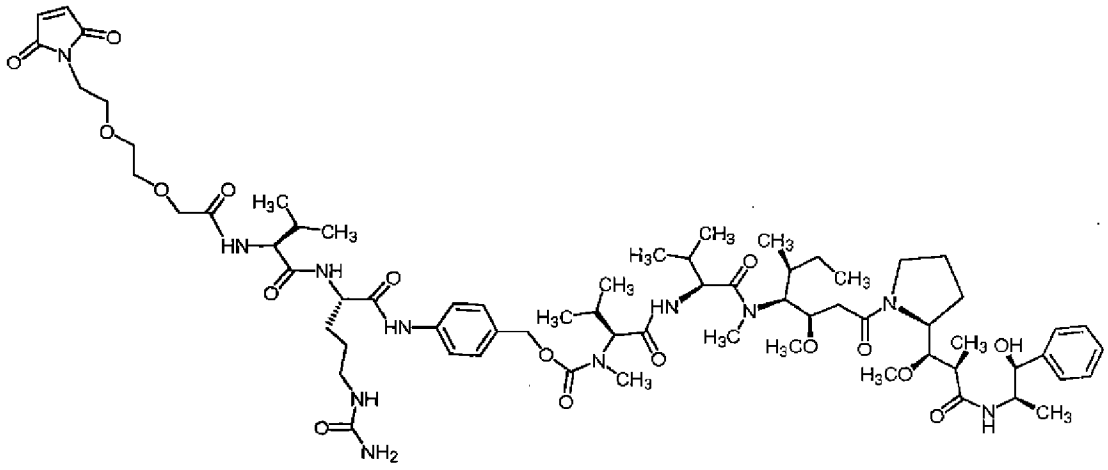
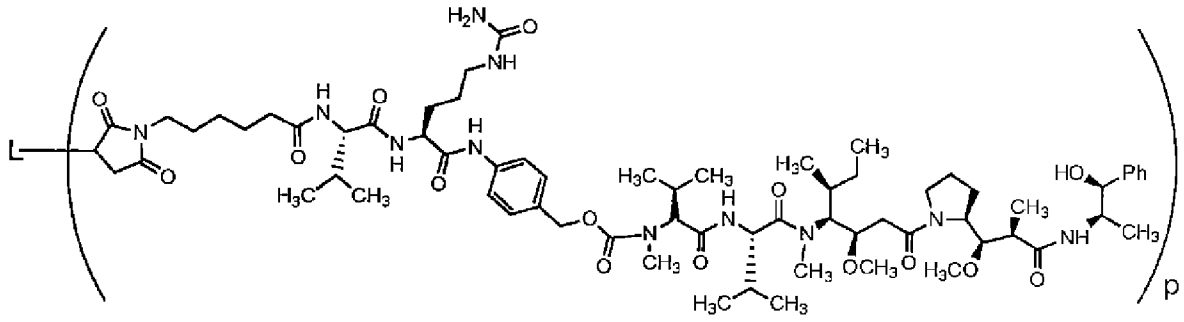


or a pharmaceutically acceptable salt thereof.

53. (Canceled)

54. (Currently amended) The compound of claim 128 having the structure:



or a pharmaceutically acceptable salt thereof.

55. (Canceled)

56. (Currently amended) The compound of claim 1 having the structure:

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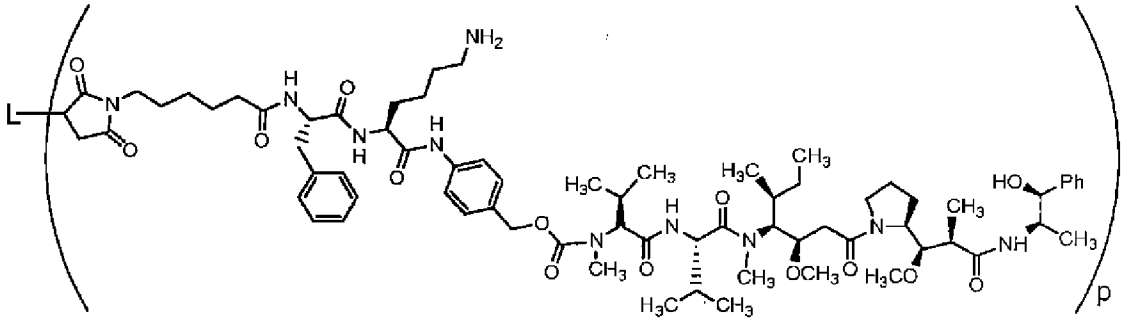
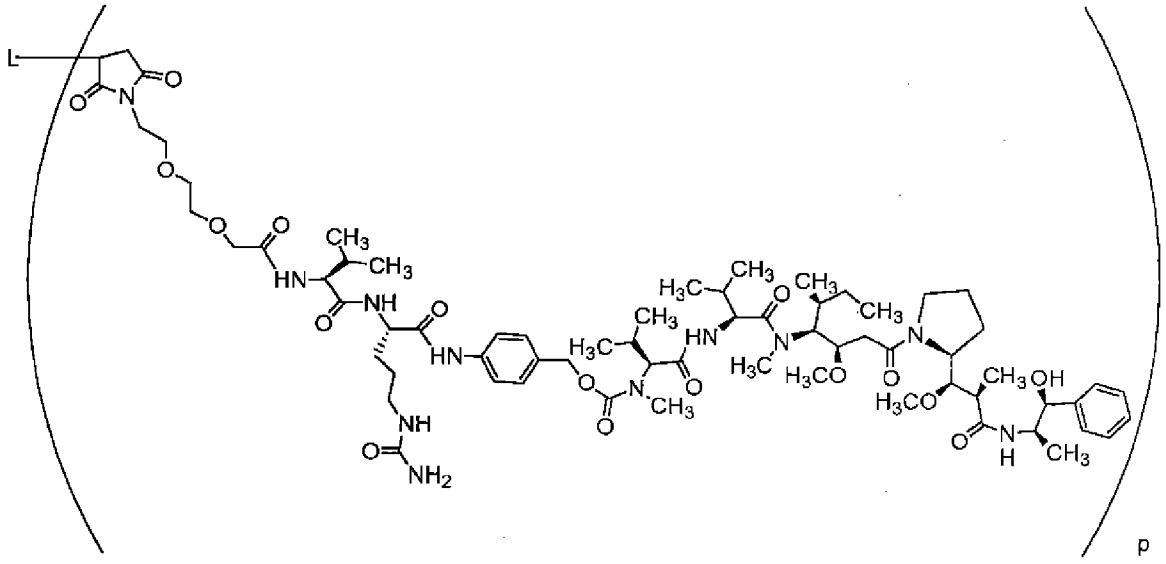


or a pharmaceutically acceptable salt thereof.

57-58. (Canceled)

59. (Currently amended) The compound of claim 1 having the structure:



or a pharmaceutically acceptable salt thereof.

60-76. (Canceled)

77. (Currently amended) The compound of claim 1 having the formula:

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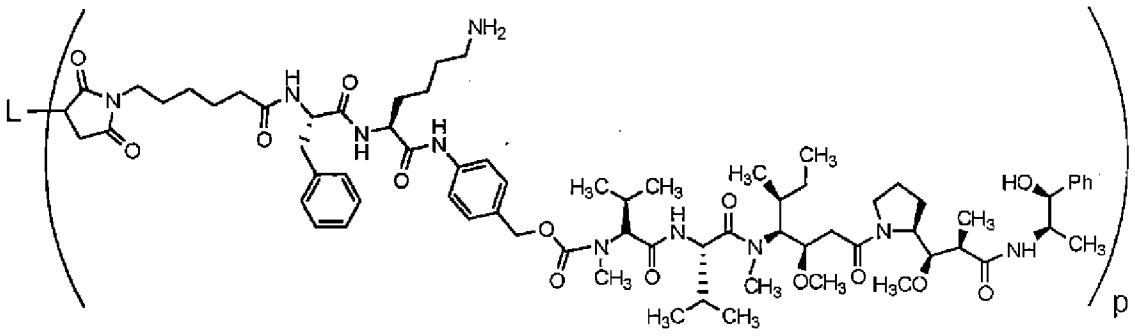

or a pharmaceutically acceptable salt thereof, wherein L is a monoclonal antibody.

78. (Canceled)

79. (Previously presented) The compound of claim 54 or a pharmaceutically acceptable salt thereof, wherein L is a monoclonal antibody.

80-99. (Canceled)

100. (Previously presented) The compound or pharmaceutically acceptable salt thereof of claim 79 wherein L specifically binds the CD20 antigen.

101-103. (Canceled)

104. (Previously presented) The compound or pharmaceutically acceptable salt thereof of claim 77 wherein L specifically binds the CD20 antigen.

105-110. (Canceled)

111. (Previously presented) A composition comprising an effective amount of a compound or a pharmaceutically acceptable salt thereof of claim 1 or claim 7, and a pharmaceutically acceptable carrier or vehicle.

112-118. (Canceled)

119. (Previously presented) The compound or a pharmaceutically acceptable salt thereof of claim 1 in an isolated or a purified form.

120. (Canceled)

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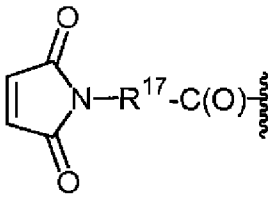
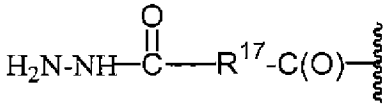
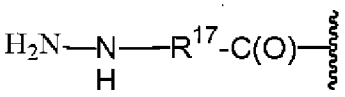
121. (Currently amended) The compound or a pharmaceutically acceptable salt of the compound of claim 1 wherein -W_w- is -valine-citrulline-, the amino terminus of -W_w- forming a bond with the Stretcher unit, and the C- terminus of -W_w- forming a bond with a the Spacer unit.

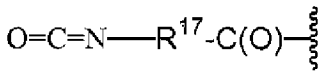
122. (Currently amended) The compound of claim 44 or a pharmaceutically acceptable salt of the compound of claim 44, wherein

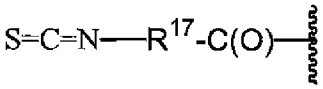
-A' is selected from the group consisting of:

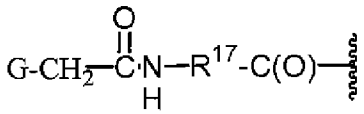

;

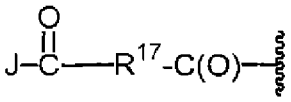

;

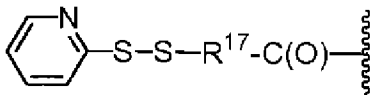

;

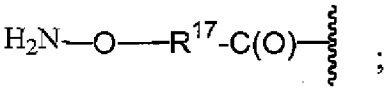

;


;


;


;


; and


;

~~wherein~~

G is selected from the group consisting of -Cl, -Br, -I, -O-mesyl and -O-tosyl;

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J is selected from the group consisting of -Cl, -Br, -I, -F, -OH, -O-N-succinimide, -O-(4-nitrophenyl), -O-pentafluorophenyl, -O-tetrafluorophenyl and -O-C(O)-OR^{18};

a is 1;

R^{17} is selected from the group consisting of -C_1-C_{10} alkylene-, -C_3-C_8 carbocyclo-, -O-(C_1-C_8 alkoxy)-, -arylene-, -C_1-C_{10} alkylene-arylene-, -arylene-C_1-C_{10} alkylene-, -C_1-C_{10} alkylene-(C_3-C_8 carbocyclo)-, -(C_3-C_8 carbocyclo)-C_1-C_{10} alkylene-, -C_3-C_8 heterocyclo-, -C_1-C_{10} alkylene-(C_3-C_8 heterocyclo)-, -(C_3-C_8 heterocyclo)-C_1-C_{10} alkylene-, -$(CH_2CH_2O)_r$-, and -$(CH_2CH_2O)_r$-CH_2-;

r is an integer ranging from 1-10; and

R^{18} is -C_1-C_8 alkyl or -aryl.

123. (Canceled)

124. (Previously presented) A composition comprising an effective amount of a compound or a pharmaceutically acceptable salt thereof of claim 79 and a pharmaceutically acceptable carrier or vehicle.

125. (Previously presented) A composition comprising an effective amount of a compound or a pharmaceutically acceptable salt thereof of claim 121 and a pharmaceutically acceptable carrier or vehicle.

126. (Previously presented) The compound or a pharmaceutically acceptable salt thereof of claim 79 in an isolated or a purified form.

127. (Previously presented) The compound or a pharmaceutically acceptable salt thereof of claim 121 in an isolated or a purified form.

128. (Previously presented) The compound or a pharmaceutically acceptable salt of the compound of claim 1 wherein

-Aa-Ww-Yy- has the formula:

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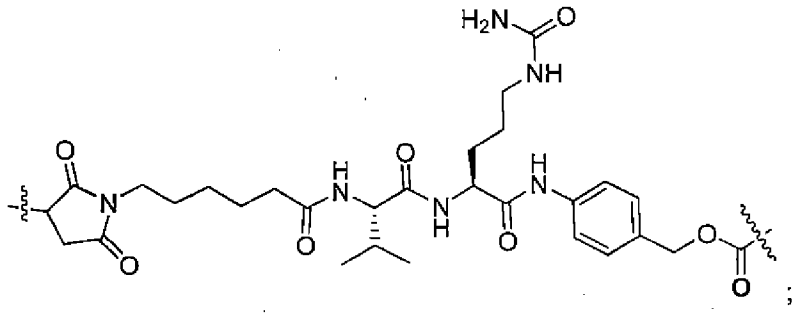
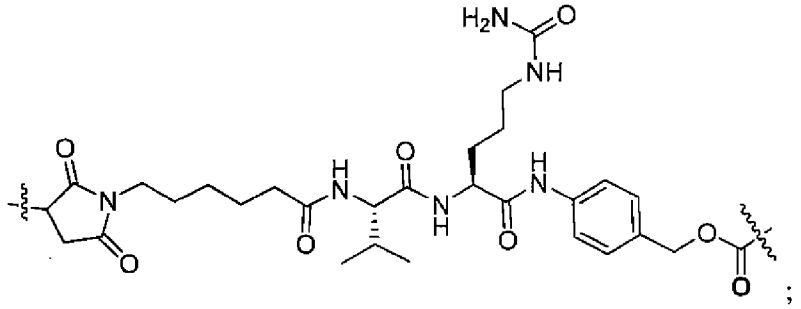


the succinimido terminus forming a bond with the Ligand unit and the other terminus forming a bond with the Drug unit.

129. (Previously presented) The compound or a pharmaceutically acceptable salt of the compound of claim 7 wherein

-Aa-Ww-Yy- has the formula:



the succinimido terminus forming a bond with the Ligand unit and the other terminus forming a bond with the Drug unit.

130. (Previously presented) The compound or a pharmaceutically acceptable salt of the compound of claims 128 or 129 wherein the ligand unit is a monoclonal antibody.

131. (Currently amended) The compound or pharmaceutically acceptable salt thereof of claim 1 wherein R^{10} is

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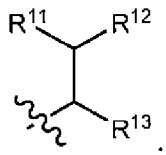
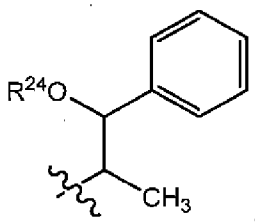


132. (Currently amended) The compound or pharmaceutically acceptable salt thereof of claim 7 wherein R^{10} is:

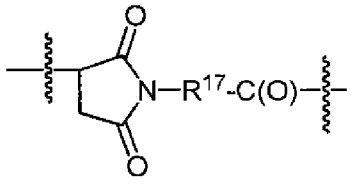


133. (Previously presented) The compound or a pharmaceutically acceptable salt of the compound of claim 19 wherein the monoclonal antibody specifically binds the CD30 antigen.

134. (Previously presented) The compound or a pharmaceutically acceptable salt of the compound of claim 19 wherein the monoclonal antibody specifically binds the CD19 antigen.

135. (Previously presented) The compound or a pharmaceutically acceptable salt of the compound of claim 19 wherein the monoclonal antibody specifically binds the CD33 antigen.

136. (Currently amended) The compound or a pharmaceutically acceptable salt of the compound of claim 1 wherein $-A_a-$ is:



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~~wherein~~ R^{17} is selected from the group consisting of -C_1-C_{10} alkylene, C_3-C_8 carbocyclo-, -O-(C_1-C_8 alkyl)-, -arylene-, -C_1-C_{10} alkylene-arylene-, -arylene-C_1-C_{10} alkylene-, -C_1-C_{10} alkylene-(C_3-C_8 carbocyclo)-, -(C_3-C_8 carbocyclo)-C_1-C_{10} alkylene-, -C_3-C_8 heterocyclo-, -C_1-C_{10} alkylene-(C_3-C_8 heterocyclo)-, - (C_3-C_8 heterocyclo)-C_1-C_{10}alkylene-, -$(CH_2CH_2O)_r$-, and -$(CH_2CH_2O)_r$-CH_2-; and r is an integer ranging from 1-10.

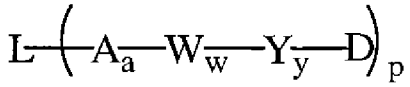
137. (Currently amended) [A]The compound or a pharmaceutically acceptable salt of the compound of claim 1 wherein p ranges from 1 to about 5.

138. (Currently amended) [A]The compound or a pharmaceutically acceptable salt of the compound of claim 79 wherein p ranges from 1 to about 5.

139. (Currently amended) [A]The compound or a pharmaceutically acceptable salt of the compound of claim 54 wherein L is a monoclonal antibody that specifically binds the CD30 antigen, the CD20 antigen, the Lewis X or Y antigen, the CD33 antigen, the CD19 antigen, the CD38 antigen, the CEA antigen, the CA15-3 antigen or the epidermal growth factor antigen.

140. (Currently amended) [A]The compound or a pharmaceutically acceptable salt of the compound of claim 139 wherein the monoclonal antibody specifically binds the CD30 antigen.

141. (Currently amended) A composition comprising drug-linker-ligand conjugates having Formula Ia:



Ia

or a pharmaceutically acceptable salt thereof;

wherein,

L- is a Ligand unit;

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-A- is a Stretcher unit;

a is 1;

each -W- is independently an Amino Acid unit;

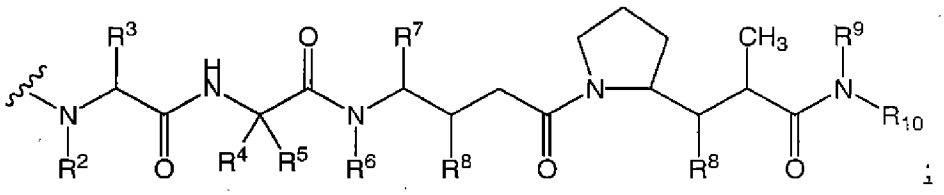
-Y- is a self-immolative Spacer unit;

w is an integer ranging from 2 to 12;

y is 1 or 2;

p ranges from 1 to about 5 and is the average number of $-A_a-W_w-Y_y-D$ units per ligand in the composition; and

-D is a Drug unit of the formula:



~~wherein,~~ the wavy line indicates the point of attachment to the Spacer unit, and independently at each location:

R^2 is selected from the group consisting of -H and $-C_1-C_8$ alkyl;

R^3 is selected from the group consisting of -H, $-C_1-C_8$ alkyl, $-C_3-C_8$ carbocycle, $-O-(C_1-C_8$ alkyl), -aryl, $-C_1-C_8$ alkyl-aryl, $-C_1-C_8$ alkyl-(C_3-C_8 carbocycle), $-C_3-C_8$ heterocycle and $-C_1-C_8$ alkyl-(C_3-C_8 heterocycle);

R^4 is selected from the group consisting of -H, $-C_1-C_8$ alkyl, $-C_3-C_8$ carbocycle, $-O-(C_1-C_8$ alkyl), -aryl, $-C_1-C_8$ alkyl-aryl, $-C_1-C_8$ alkyl-(C_3-C_8 carbocycle), $-C_3-C_8$ heterocycle and $-C_1-C_8$ alkyl-(C_3-C_8 heterocycle) ~~wherein;~~ R^5 is selected from the group consisting of -H and -methyl; or R^4 and R^5 join and form a ring with the carbon atom to which they are attached and R^4 and R^5 have the formula $-(CR^aR^b)_n-$ ~~wherein;~~ R^a and R^b are independently selected from the group consisting of -H, $-C_1-C_8$ alkyl and $-C_3-C_8$ carbocycle and n is selected from the group consisting of 2, 3, 4, 5 and 6;

R^6 is selected from the group consisting of -H and $-C_1-C_8$ alkyl;

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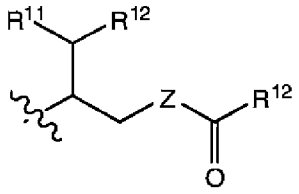
R^7 is selected from the group consisting of -H, -C_1-C_8 alkyl, -C_3-C_8 carbocycle, -O-(C_1-C_8 alkyl), -aryl,
-C_1-C_8 alkyl-aryl, -C_1-C_8 alkyl-(C_3-C_8 carbocycle), -C_3-C_8 heterocycle and -C_1-C_8 alkyl-(C_3-C_8 heterocycle);

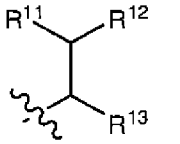
each R^8 is independently selected from the group consisting of -H, -OH, -C_1-C_8 alkyl, -C_3-C_8 carbocycle and -O-(C_1-C_8 alkyl);

R^9 is selected from the group consisting of -H and -C_1-C_8 alkyl;

R^{10} is selected from the group consisting of:



and



Z is -O-, -S-,-NH- or -N(R^{14})-;

R^{11} is selected from the group consisting of -H, -OH, -NH_2, -NHR^{14}, -N(R^{14})$_2$, -C_1-C_8 alkyl, -C_3-C_8 carbocycle, -O-(C_1-C_8 alkyl), -aryl, -C_1-C_8 alkyl-aryl, -C_1-C_8 alkyl-(C_3-C_8 carbocycle), -C_3-C_8 heterocycle and -C_1-C_8 alkyl-(C_3-C_8 heterocycle); or R^{11} is an oxygen atom which forms a carbonyl unit (C=O) with the carbon atom to which it is attached and a hydrogen atom on this carbon atom is replaced by one of the bonds in the (C=O) double bond;

each R^{12} is independently selected from the group consisting of -aryl and -C_3-C_8 heterocycle;

R^{13} is selected from the group consisting of -H, -OH, -NH_2, -NHR^{14}, -N(R^{14})$_2$, -C_1-C_8 alkyl, -C_3-C_8 carbocycle, -O-(C_1-C_8 alkyl), -aryl, -C_1-C_8 alkyl-aryl, -C_1-C_8 alkyl-(C_3-C_8 carbocycle), C_3-C_8 heterocycle and -C_{1-8} alkyl-(C_3-C_8 heterocycle); and

each R^{14} is independently -H or -C_1-C_8 alkyl.

142. (Currently amended) A composition comprising drug-linker-ligand conjugates having Formula Ia:

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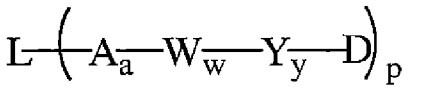


Ia ;

or a pharmaceutically acceptable salt thereof

wherein,

L- is a Ligand unit;

-A- is a Stretcher unit;

a is 1;

each -W- is independently an Amino Acid unit;

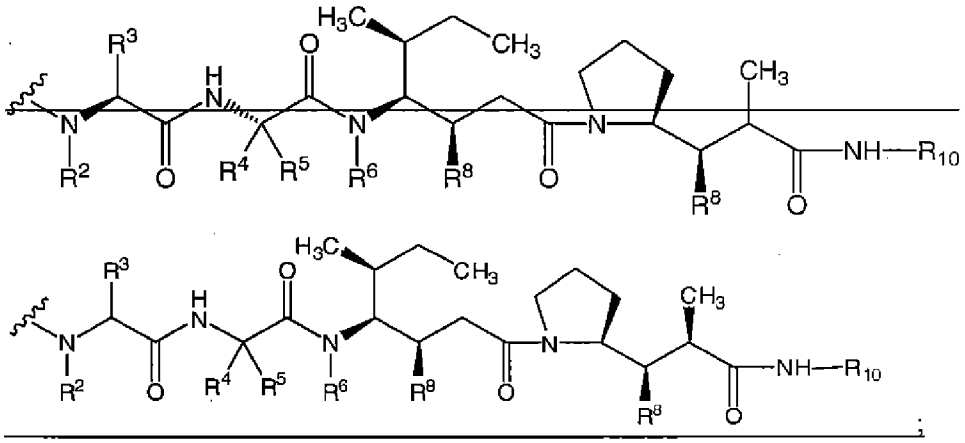
-Y- is a self-immolative Spacer unit;

w is an integer ranging from 2 to 12;

y is 1 or 2;

p ranges from 1 to about 5 and is the average number of $-A_a-W_w-Y_y-D$ units per ligand in the composition; and

-D is a Drug unit having the structure:



~~or a pharmaceutically acceptable salt thereof,~~

~~wherein,~~ the wavy line [is]indicates the point of attachment to the Spacer unit, and

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independently at each location:

R^2 is selected from the group consisting of -H and -methyl;

R^3 is selected from the group consisting of -H, -methyl, and -isopropyl;

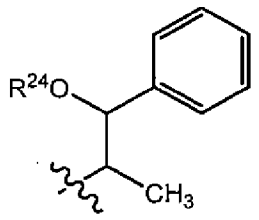
R^4 is selected from the group consisting of -H and -methyl;

R^5 is selected from the group consisting of -isopropyl, -isobutyl, -sec-butyl, -methyl and -t-butyl or R^4 and R^5 join[,] and form a ring with the carbon atom to which they are attached and R^4 and R^5 have the formula $-(CR^aR^b)_n-$ ~~where;~~ R^a and R^b are independently selected from the group consisting of -H, $-C_1$-C_8 alkyl, and
$-C_3$-C_8 carbocycle, and n is selected from the group consisting of 2, 3, 4, 5 and 6;

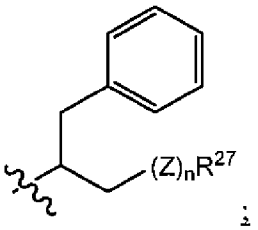
R^6 is selected from the group consisting of -H and -methyl;

each R^8 is independently selected from the group consisting of -OH, -methoxy and -ethoxy;

R^{10} is selected from the group consisting of:



and



;

R^{24} is selected from the group consisting of H and $-C(O)R^{25}-$; ~~wherein;~~ R^{25} is selected from the group consisting of $-C_1$-C_8 alkyl, $-C_3$-C_8 carbocycle, -aryl, $-C_1$-C_8 alkyl-aryl, $-C_1$-C_8 alkyl-(C_3-C_8 carbocycle), $-C_3$-C_8 heterocycle and $-C_1$-C_8 alkyl-(C_3-C_8 heterocycle);

Z is -O-, -NH-, -OC(O)-, -NHC(O)-, or $-NR^{28}C(O)-$; ~~where;~~ R^{28} is selected from the group consisting of -H and $-C_1$-C_8 alkyl;

n is 0 or 1; and

R^{27} is selected from the group consisting of -H, $-N_3$, $-C_1$-C_8 alkyl, $-C_3$-C_8 carbocycle, -aryl, $-C_1$-C_8 alkyl-aryl, $-C_1$-C_8 alkyl-(C_3-C_8 carbocycle), $-C_3$-C_8 heterocycle and $-C_1$-C_8 alkyl-(C_3-C_8 heterocycle) when n is 0; and

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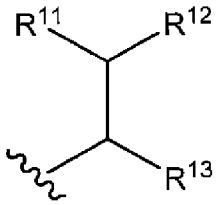
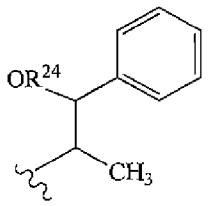
R^{27} is selected from the group consisting of -H, -C_1-C_8 alkyl, -C_3-C_8 carbocycle, -aryl, -C_1-C_8 alkyl-aryl,
-C_1-C_8 alkyl-(C_3-C_8 carbocycle), -C_3-C_8 heterocycle and -C_1-C_8 alkyl-(C_3-C_8 heterocycle) when n is 1.

143. (Currently amended) The composition of claim 141 wherein in the drug-linker-ligand conjugates or pharmaceutically acceptable salt thereof; R^{10} is



144. (Currently amended) The composition of claim 142 wherein in the drug-linker-ligand conjugates or pharmaceutically acceptable salt thereof; R^{10} is



145. (Currently amended) The composition of claim 141 wherein in the drug-linker-ligand conjugates or pharmaceutically acceptable salt thereof; -D is a Drug unit having the structure:

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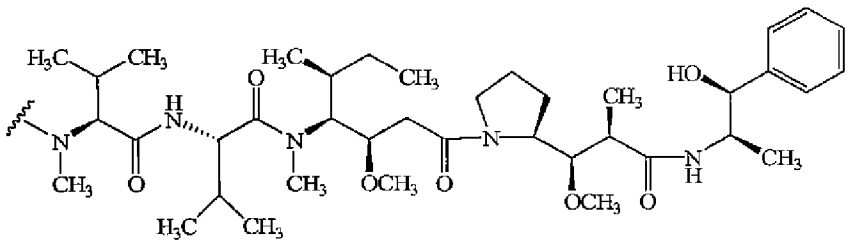
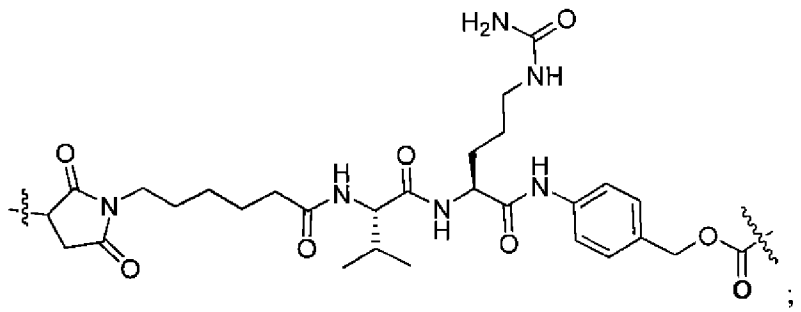


~~or a pharmaceutically acceptable salt thereof.~~

146. (Currently amended) The composition of claim 141 wherein in the drug-linker-ligand conjugates or pharmaceutically acceptable salt thereof; -Aa-Ww-Yy- has the formula:



the succinimido terminus forming a bond with the Ligand unit and the other terminus forming a bond with the Drug unit.

147. (Currently amended) The composition of claim 142 wherein in the drug-linker-ligand conjugates or pharmaceutically acceptable salt thereof; -Aa-Ww-Yy- has the formula:

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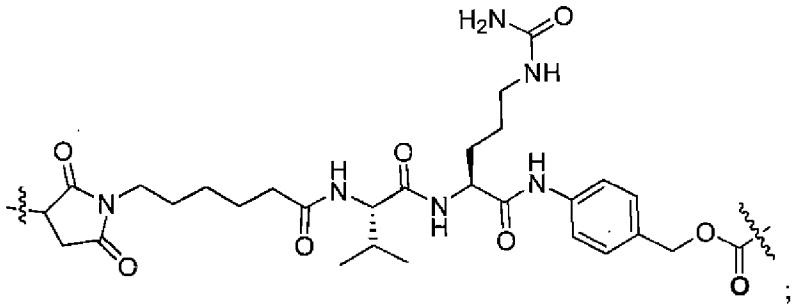

the succinimido terminus forming a bond with the Ligand unit and the other terminus forming a bond with the Drug unit.

148. (Currently amended) The composition of claim 141 wherein in the drug-linker-ligand conjugates or pharmaceutically acceptable salt thereof; the ligand unit is a monoclonal antibody.

149. (Currently amended) The composition of claim 148 wherein in the drug-linker-ligand conjugates or pharmaceutically acceptable salt thereof; the monoclonal antibody specifically binds the CD30 antigen, the CD20 antigen, the CD19 antigen, the Lewis X or Y antigen, the CD33 antigen, the CD38 antigen, the CEA antigen, the CA15-3 antigen or the epidermal growth factor antigen.

150. (Currently amended) The composition of 149 wherein in the drug-linker-ligand conjugates or pharmaceutically acceptable salt thereof; the monoclonal antibody specifically binds the CD19 antigen.

151. (Currently amended) The composition of claim 149 wherein in the drug-linker-ligand conjugates or pharmaceutically acceptable salt thereof; the monoclonal antibody specifically binds the CD30 antigen.

152. (Currently amended) The composition of claim 149 wherein in the drug-linker-ligand conjugates or pharmaceutically acceptable salt thereof; the monoclonal antibody specifically binds the CD33 antigen.

153. (Currently amended) The composition of claim 147 wherein the drug-linker-ligand conjugates have the formula:

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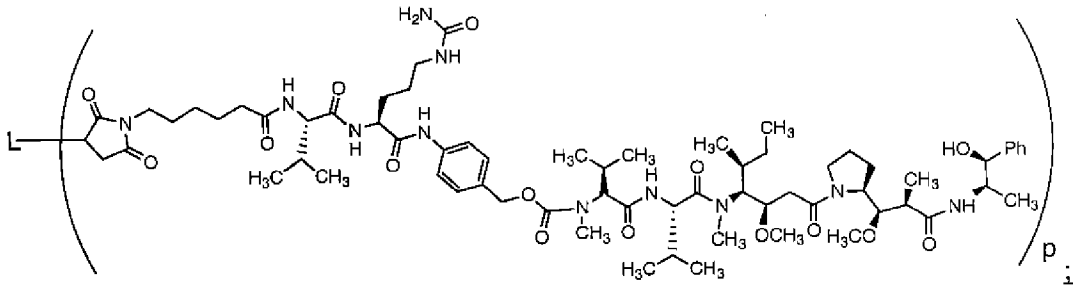

or a pharmaceutically acceptable salt thereof.

154. (Currently amended) The composition of claim 153 wherein in the drug-linker-ligand conjugates or pharmaceutically acceptable salt thereof; L is a monoclonal antibody.

155. (Currently amended) The composition of claim 154 wherein in the drug-linker-ligand conjugates or pharmaceutically acceptable salt thereof; the monoclonal antibody specifically binds the CD20 antigen, the CD30 antigen, the CD33 antigen, the CD19 antigen, the CD38 antigen, the CA15-3 antigen, the CEA antigen, or the epidermal growth factor antigen.

156. (Currently amended) The composition of claim 155 wherein in the drug-linker-ligand conjugates or pharmaceutically acceptable salt thereof; the monoclonal antibody specifically binds the the CD30 antigen.

157. (Currently amended) The composition of claim 155 wherein in the drug-linker-ligand conjugates or pharmaceutically acceptable salt thereof; the monoclonal antibody specifically binds the CD19 antigen.

158. (Currently amended) The composition of claim 155 wherein in the drug-linker-ligand conjugates or pharmaceutically acceptable salt thereof; the monoclonal antibody specifically binds the CD20 antigen.

159. (Currently amended) The composition of claim 155 wherein in the drug-linker-ligand conjugates or pharmaceutically acceptable salt thereof; the monoclonal antibody specifically binds the CD33 antigen.

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160. (Currently amended) The composition of claim 142 wherein in the drug-linker-ligand conjugates or pharmaceutically acceptable salt thereof; L is a monoclonal antibody.

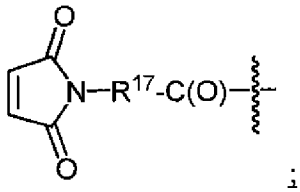
161. (Currently amended) The composition of claim 160 wherein in the drug-linker-ligand conjugates or pharmaceutically acceptable salt thereof; the monoclonal antibody specifically binds the CD20 antigen, the CD30 antigen, the CD33 antigen, the CD19 antigen, the CD38 antigen, the CA15-3 antigen, the CEA antigen, or the epidermal growth factor antigen.

162. (Currently amended) The composition of claim 161 wherein in the drug-linker-ligand conjugates or pharmaceutically acceptable salt thereof; the monoclonal antibody specifically binds the CD30 antigen.

163. (Currently amended) The composition of claim 154 wherein in the drug-linker-ligand conjugates or pharmaceutically acceptable salt thereof; the antibody is attached to the drug moiety through a cysteine residue of the antibody.

164. (Currently amended) The compound of claim 122 or a pharmaceutically acceptable salt of the compound of claim 122, wherein

A_a- is:



~~wherein~~ R^{17} is selected from the group consisting of -C_1-C_{10} alkylene, C_3-C_8 carbocyclo-, -O-(C_1-C_8 alkyl)-, -arylene-, -C_1-C_{10} alkylene-arylene-, -arylene-C_1-C_{10} alkylene-, -C_1-C_{10} alkylene-(C_3-C_8 carbocyclo)-, -(C_3-C_8 carbocyclo)-C_1-C_{10} alkylene-, -C_3-C_8 heterocyclo-, -C_1-C_{10} alkylene-(C_3-C_8 heterocyclo)-, - (C_3-C_8 heterocyclo)-C_1-C_{10}alkylene-, -$(CH_2CH_2O)_r$-, and -$(CH_2CH_2O)_r$-CH_2-; and r is an integer ranging from 1-10.

165. (Previously presented) The compound of claim 1 or a pharmaceutically acceptable salt of the compound wherein R^2 is -C_1-C_8 alkyl.

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166. (Currently amended) The composition of claim 141 wherein in the drug-linker-ligand conjugates or pharmaceutically acceptable salt thereof; R^2 is -C_1-C_8 alkyl.

167. (Previously presented) The compound of claim 7 or a pharmaceutically acceptable salt of the compound wherein R^2 is –methyl.

168. (Currently amended) The composition of claim 142 wherein in the drug-linker-ligand conjugates or pharmaceutically acceptable salt thereof; R^2 is –methyl.

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REMARKS/ARGUMENTS

This Amendment is being filed after receiving a Notice of Allowance mailed on September 25, 2009. Pending claims 1, 7, 9, 17-30, 44-46, 48, 52, 54, 56, 59, 77, 79, 100, 104, 111, 119, 121, 122, 124-168 have been allowed. The Examiner is thanked for the Notice of Allowance.

In this amendment pursuant to 37 C.F.R. 1.312, the paragraph at page 1 between the Title of the application and Field of Invention has been amended to specify that the application was filed under 35 U.S.C. § 371 as a national stage application of International Application No. PCT/US2003/24209, as acknowledged in the Official Filing Receipt mailed November 21, 2005.

Claims 1, 7, 9, 17-30, 44-46, 48, 52, 54, 56, 59, 77, 122, 131, 132, and 136-168 are also amended. Claims 1, 7, 20-29, 44-46, 48, 52, 54, 56, 59, 77, 150, 153, and 157 have been amended to add punctuation within the claims. Claims 7 and 142 have been amended to delete the redundant second use of the phrase "or a pharmaceutically acceptable salt thereof. Claims 7 and 142 has been amended to replace the phrase "the wavy line is" with the phrase "the wavy line indicates." Dependent claims 9, 17 and 137-140 have been amended to replace the term "a" with the term "the." Claims 18-30, 121, 131-132, 139, 145 and 148 have been amended to replace the term "where" with the term "wherein." Claims 7, 44, 122, 136, 141, 142 and 164 are amended to add a colon and semicolon, and to delete the redundant second use of the term "wherein" and/or "where". Claims 143-152, 154-163, 166 and 168 are amended to clarify that the scope of the claims includes a pharmaceutically acceptable salt of the drug-linker-ligand conjugates. Claim 145 has been amended to move the location of the recitation concerning a pharmaceutically acceptable salt for consistency purposes.

Applicants also note that the term "or" was deleted but not shown as an amendment in the amendment filed July 30, 2008 in response to the Office Action of April 29, 2008. This term is deleted in claim 1 herein. Applicants also note that the structure of the Drug unit, D, was changed but not shown as an amendment in the amendment filed July 30, 2008 in response to the Office Action of April 29, 2008. Claim 7 should have the original structure as

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depicted in the claims herein. Claim 142 is amended to replace the structure of the Drug unit, D, with this original structure.

Applicant submits that no new subject matter has been introduced by virtue of these amendments. Because this amendment merely cures formal defects in some of the claims and does not touch the merits, no additional search is required and no more than a cursory review of the record is needed, and therefore the amendments do not require a substantial amount of work on the part of the Office. Applicant respectfully requests that these amendments be entered prior to issuance of the application.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,

DRAFT

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